THE UNIVERSITY OF BRITISH COLUMBIA
Division of Gastroenterology

PARTICIPANT INFORMATION AND CONSENT FORM

FOCUS: The Future of Fecal Calprotectin Utility Study for the diagnosis and management of IBD.

Principal investigator:
Brian Bressler, MD
Department of Medicine, Division of Gastroenterology, UBC
604-688-6332

Co- Investigators:
Greg Rosenfeld, MD
Department of Medicine, Division of Gastroenterology, UBC

Christina Beerens
Study Coordinator, UBC

INTRODUCTION

We are inviting you to participate in a research study of men and women, who are suspected of having inflammatory bowel disease (IBD), to better understand the role of a laboratory test in the management of patient's symptoms.

YOUR PARTICIPATION IS VOLUNTARY

Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services to which you are entitled or are presently receiving.

Before you decide, it is important for you to understand what the research involves. This consent form will tell you about the study, why the research is being done, what will happen to you during the study and the possible benefits, risks and discomforts. You also need to know that there are important differences between being in a research study and being cared for by your doctor. When you participate in a research study, the main goal is to learn things to help other patients in the future. Outside a research study, your doctor's sole goal is to care for your health. Nevertheless, the researchers have a duty of care to all participants and will inform you of any information that may affect your willingness to remain in the study.

If you do decide to take part in this study, you are still free to withdraw without giving any reasons for your decision.

If you do not wish to participate, you do not have to provide any reason for this.

WHO IS CONDUCTING THIS STUDY?
The study is being conducted by Dr. Brian Bressler in the UBC Division of Gastroenterology. His co-investigator is Dr. Greg Rosenfeld of the UBC Division of Gastroenterology.

BACKGROUND
The human intestine contains many different cell types, including those that are part of the immune system which is responsible for fighting infection in the human body. Calprotectin is a protein found inside the cells of the immune system within the intestine known as neutrophils, granulocytes and macrophages. Inflammatory bowel disease (IBD) is a condition whereby the intestine becomes inflamed and the number of immune system cells within the wall of the intestine increases. In this situation, calprotectin is released from the immune cells into the bowel and excreted in the stool. Fecal Calprotectin levels can be measured and serve as a biological marker of the degree of inflammation in the bowel. Therefore, Fecal Calprotectin can be used to assess the disease activity of IBD and specifically for Crohn's Disease and Ulcerative Colitis which are the two main forms of IBD.

The Fecal Calprotectin test is sensitive and specific for intestinal inflammation and has the advantage of being simple and non-invasive. Fecal Calprotectin has previously been shown to correlate closely with degree of IBD activity seen on endoscopic examination (colonoscopy or flexible sigmoidoscopy). The test has also been shown to be useful in distinguishing organic bowel disease such as IBD from other causes of gastrointestinal symptoms such as irritable bowel syndrome. However, the best use of the test in clinical practice has yet to be determined. While approved by Health Canada, the Fecal Calprotectin test is not widely available and therefore, does not form part of the usual standard of care.

WHAT IS THE PURPOSE OF THIS STUDY?
We hope to assess how the Fecal Calprotectin (FC) test could best be utilized to improve the care of patients with gastrointestinal symptoms. The impact of the Fecal Calprotectin result on the physician's choice of treatment will be assessed through the use of an online survey.

There are 4 primary situations in which the test is most likely to be utilized:

1. For patients not known to have IBD, who present with intestinal symptoms where the FC could be used to determine the presence or absence of organic disease.

2. For patients with known IBD who have a flare of symptoms where the FC may help to determine if the increase in symptoms represent a recurrence of IBD.
3. To serve as a measure of the effectiveness of therapy for IBD. To tell us when patients have achieved mucosal healing with therapy based on a negative FC result.
4. To help determine when patients should restart medical therapy after surgery for IBD.

WHO CAN PARTICIPATE IN THIS STUDY?

This study is open to individuals who have been assessed by a gastroenterologist who has recommended that they undergo a fecal calprotectin test. This will most commonly be for individuals with symptoms suggestive of IBD but have not been diagnosed with IBD or who those who are known to have IBD and have symptoms that suggest a change in the severity of their disease or a lack of response to therapy for IBD. You must be able to speak and understand English and must be at least 19 years of age or older. Anyone who meets these criteria is eligible to participate.

WHO SHOULD NOT PARTICIPATE IN THE STUDY?

This study will not be suitable for anyone who is not fluent in English. Anyone with known Ischemic colitis, infectious enteritis or colitis, known colorectal cancer, a history of extensive bowel resection (subtotal colectomy, > 3 bowel resections), an ostomy, an ileoanal pouch, current daily use of non-steroidal anti-inflammatory drugs, such as aspirin or ibuprofen, or is unable to collect a stool sample and return it within 3 days should not participate.

WHAT DOES THE STUDY INVOLVE?

Those who are interested in participating in the study will meet a research nurse or assistant, at the office of the participant's gastroenterologist. The research assistant or nurse will explain the research project in more detail and obtain written informed consent. Participants will be asked to give permission for the gastroenterologist to provide the investigators with information about their condition including demographic information such as age, duration of disease or symptoms, severity of disease/symptoms, information about previous investigations including endoscopic examinations, Computed Tomography scans or x-rays and bloodwork. As well, the doctor will share with the investigators how the FC level impacted any decisions made about a participant's treatment and management. Your gastroenterologist will complete two surveys; one when the FC test is requested and a second one when the FC result is received. This information will be entered into an online, secure website and all of the participant's identifying information will be removed and replaced with a unique alphanumeric code. Only your physician will have the key to the code to identify you and

the result of your Fecal Calprotectin test. The study will end after your doctor completes the second survey.

WHAT ARE MY RESPONSIBILITIES?
You will be required to collect a first morning stool sample within three days of enrolling in the study. The stool sample will then need to be dropped into a mailbox for delivery to the Gastrointestinal Research Institute (GIRI) where the sample will be processed. You will need to schedule a follow up appointment with your gastroenterologist 2-3 weeks after mailing your stool sample to GIRI in order to discuss the results of your test. All of the necessary materials to collect the sample and mail it to GIRI will be provided at no cost to you.

WHAT ARE THE POSSIBLE HARMS AND SIDE EFFECTS OF PARTICIPATING?
There are no side effects to the test. However, as with any test, there is a risk of a false positive result which could lead your physician to recommend to you further investigations such as a colonoscopy and biopsy which may not have otherwise been recommended.

Some people may find collection of stool samples unpleasant or difficult.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?
There may or may not be direct benefits to you from taking part in this study. A negative test may mean that you will not need to undergo a colonoscopy that might have been necessary without the Fecal Calprotectin results. By participating you may be able to get feedback about your symptoms and a diagnosis faster than having to wait for standard care (a colonoscopy). Fecal Calprotectin levels may allow for improved control of your symptoms and modifications in therapy that would not be possible otherwise.

WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?
Your participation in this research is entirely voluntary. If you decide to withdraw, there will be no penalty to you.

WHAT WILL THE STUDY COST ME?
There will be no cost to you for participating in this study nor will you be paid for your participation.

WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?
Your confidentiality will be respected. No information that discloses your identity will be released or published without your specific consent to the disclosure. However, research records and medical records identifying you may be inspected in the presence of the Investigator by UBC Research Ethics Board for the purpose of monitoring the

research. However, no records which identify you by name or initials will be allowed to leave the Investigators' offices.

You will be assigned a unique study number as a participant in this study. Only this number will be used on any research-related information collected about you during the course of this study, so that your identity [i.e. your name or any other information that could identify you] as a participant in this study will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to insure that your privacy is respected and also give you the right of access to the information about you that has been provided to the study Investigators and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study doctor.

WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY DURING MY PARTICIPATION?

If you have any questions or desire further information about this study you can contact Dr. Bressler at 604-688-6332 or Christina Beerens at 604-688-6332 ext 247.

WHO DO I CONTACT IF I HAVE ANY QUESTIONS OR CONCERNS ABOUT MY RIGHTS AS A PARTICIPANT DURING THE STUDY?

If you have any concerns about your rights as a research participant and/or your experiences while participating in this study, contact the Research Subject Information Line in the University of British Columbia Office of Research Services at 604-822-8598 or if long distance email to RSIL@ors.ubc.ca.

FOCUS: The Future of Fecal Calprotectin Utility Study for the diagnosis and management of IBD.

PARTICIPANT CONSENT TO PARTICIPATE:

My signature on this consent form means:

- I have read and understood the participant information and consent form.
- I have had sufficient time to consider the information provided and to ask for advice if necessary.
- I have had the opportunity to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific objectives.
- I understand that my participation in this study is voluntary and that I am completely free to refuse to participate or to withdraw from this study at any time without changing in any way the quality of care that I receive.
- I authorize access to my health record and stool samples as described in this consent form.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I understand that there is no guarantee that this study will provide any benefits to me

I will receive a signed copy of this consent form for my own records.

I consent to participate in this study.

_____	_____	_____
Participant's Signature	Printed name	Date